K011986

APR 0 3 2002

6.0 Summary of Safety and Effectiveness for the SAFE-STEER™ Guide Wire System

6.1 **Trade Name:** SAFE-STEER™ Guide Wire System

Common Name: Guide Wire, Cardiovascular or Peripheral

Classification: DQX, Title 21 CFR Section: 870.1330

6.2 **Manufacturer:**

IntraLuminal Therapeutics, Inc.
6354 Corte Del Abeto
Carlsbad, CA 92009
Phone: (760) 918-1820
Fax: (760) 918-1823

Contact:

Pamela L. Misajon
Vice President of Regulatory Affairs and
Quality Assurance

Date of Preparation: March 28, 2002

6.3 **Substantially Equivalent Legally Marketed Devices:**

Product Name	510(k) Numbers
1. ACS Hi-Torque Cross-it Guide Wire	K981381 & K990639
2. ACS Hi-Torque Standard Guide Wire	K881897 & K881787

6.4 **Device Description:**

The IntraLuminal Therapeutics, Inc. SAFE-STEER™ Guide Wire System is comprised of a sterile single-use guide wire with an integrated optical fiber. The guide wire is used with a support catheter of choice that will accommodate a .014" guidewire. The optical fiber in the guide wire is connected to a reusable Optical Coherence Reflectometry (OCR). The guide wire core has an embedded optical fiber that transmits near infrared light and the reflection is relayed back to the OCR unit and then a unique intensity versus distance measurement is exhibited on the OCR display. The trace of the slope on the OCR display distinguishes the distance from the tip of the wire and the vessel wall. The display output exhibits the relative distance between the wire tip and vessel wall. The guide wire is provided in lengths of 175 cm and 275 cm long and has a diameter of 0.014" with a lubricious hydrophilic coating in the distal region. The guide wire is sterilized by ethylene oxide and packaged to maintain the sterile barrier.

6.0 Summary of Safety and Effectiveness for the SAFE-STEER™ Guide Wire System (continued)

6.5 Intended Use

The Safe-Steer™ Guide Wire System is indicated for use in facilitating the placement of catheters used in percutaneous interventions in native coronary arteries with total occlusions.

6.6 Technological Characteristics of Substantial Equivalence

The IntraLuminal Therapeutics SAFE-STEER™ Guide Wire System is comprised of a guide wire used with a support catheter of choice to facilitate the placement of catheters used in percutaneous interventions in native coronary arteries with total occlusions.

The indications for use are similar to both the ACS Hi-Torque Standard and the ACS Hi-Torque Cross-It guide wires. The models and sizes are similar to commercially distributed guide wires.

6.7 Performance Data

Safety and performance testing was performed to demonstrate that the IntraLuminal Therapeutics SAFE-STEER™ Guide Wire System is substantially equivalent to the predicate devices.

The testing included software, performance, biocompatibility, packaging, clinical and comparative tests.

6.8 **Conclusion:** In conclusion, the IntraLuminal Therapeutics SAFE-STEER™ Guide Wire System meets the requirements for being substantially equivalent to predicate devices and meets internal product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Pamela L. Misajon
Vice President of Regulatory Affairs and
Quality Assurance
IntraLuminal Therapeutics, Inc.
6354 Corte Del Abeto
Carlsbad, CA 92009

APR 0 3 2002

Re: K011986
Trade Name: SAFE-STEER™ Guide Wire System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: January 28, 2001
Received: January 29, 2001

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K011986

Device Name: IntraLuminal Therapeutics, Inc. SAFE-STEER™ Guide Wire System

Indications For Use: The Safe-Steer™ Guide Wire System is indicated for use in facilitating the placement of catheters used in percutaneous interventions in native coronary arteries with total occlusions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices

510(k) Number K011986